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No. 93-7

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In the Supreme Court of the United States

OCTOBER TERM, 1993

AMERICAN DENTAL ASSOCIATION, PETITIONER

v.

ROBERT B. REICH, SECRETARY OF LABOR, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether OSHA was justified in including dental care workers in its finding that workers in the health care industry face a significant risk of harm from exposure to bloodborne pathogens.

2. Whether OSHA improperly failed to adopt a more cost-effective alternative to the bloodborne pathogens standard.

3. Whether the court of appeals misapprehended or grossly misapplied the substantial evidence standard of review.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-52a) is reported at 984 F.2d 823.

JURISDICTION

The judgment of the court of appeals was entered on January 28, 1993. A petition for rehearing was denied on May 27, 1993. The petition for a writ of certiorari was filed on June 28, 1993. This Court's jurisdiction is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. On December 6, 1991, the Occupational Safety and Health Administration (OSHA) issued a final

standard governing occupational exposure to bloodborne pathogens. Pet. App. 2a; 29 C.F.R. 1910.1030 (see 56 Fed. Reg. 64,004-64,182 (1991)). Petitioner has challenged the rule insofar as it applies to dental care employers.

a. The bloodborne pathogens standard was designed to eliminate or minimize grave health risks from occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other bloodborne pathogens. Pet. App. 2a; 56 Fed. Reg. 64,004-64,182.[1] A person infected with HBV has a 1 in 3 chance of contracting acute hepatitis, a serious and (in about 1% of infections) fatal liver disease. Pet. App. 3a; 56 Fed. Reg. 64,009. In addition, a significant percentage (6-10%) of individuals infected with HBV become chronic HBV carriers, who are capable of passing the infection on to others and are subject to a high risk of developing serious and potentially fatal diseases, including hepatitis, cirrhosis of the liver and primary liver cancer. Pet. App. 3a; 56 Fed. Reg. 64,009. HBV can be transmitted in the workplace through blood-to-blood contact (as when a health care employee suffers a puncture wound or cut contaminated with an infected individual's blood) or through the virus's contact with the mucous membranes in an employee's eyes or mouth. Pet. App. 2a, 3a; 56 Fed. Reg. 64,010. HBV can survive for at least a week at room temperature and infection has been shown to result from contact with

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[1] A bloodborne pathogen is a disease-causing microorganism found in blood that can be transmitted from an infected individual to others through exposure to the infected person's blood or other body fluids. See 29 C.F.R. 1910.1030(b); 56 Fed. Reg. 64,008.

environmental surfaces. Pet. App. 3a; 56 Fed. Reg. 64,010. A vaccination exists for HBV that produces antibodies in, and hence is effective for, 85% to 97% of persons to whom it is administered. Pet. App. 3a; 56 Fed. Reg. 64,012.

Infection with HIV leads to acquired immune deficiency syndrome (AIDS), a disease that to date has proven invariably fatal. 56 Fed. Reg. 64,006. Although HIV is less easily transmitted than HBV, HIV can also be spread by the type of blood-to-blood contact that may occur in a health care setting, as in a needlestick, or when blood contacts an employee's non-intact skin or mucous membranes. Pet. App. 2a-3a; 56 Fed. Reg. 64,016, 64,017.[2]

b. OSHA's bloodborne pathogens standard applies to employees who may reasonably anticipate skin, eye, or mucous membrane contact with blood in the performance of their duties. 29 C.F.R. 1910.1030(a) and (b). Because saliva often becomes contaminated with blood during dental procedures, 56 Fed. Reg. 64,103, the standard includes "saliva in dental procedures" as a potentially infectious material. 29 C.F.R. 1910.1030 (b)(1). The standard is modeled to a significant degree on guidelines issued by the Centers for Disease Control and Prevention (CDC) as they existed at the time of the rule's promulgation, although the standard is more detailed and contains additional requirements. 56 Fed. Reg. 64,007. Like the CDC guidelines, the standard is based on the principle of "universal precautions," which means

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[2] Other diseases that can be transmitted through bloodborne pathogens include hepatitis C, syphilis, and malaria. 56 Fed. Reg. 64,013, 64,022-64,023.

that precautions apply to contact with blood and other potentially infectious material of every patient, not just those known or believed to be carriers of HBV or HIV. Pet. App. 3a.[3]

The precautions required by the standard include: engineering controls (such as the provision of appropriate containers for disposing of contaminated sharp instruments, like needles), 29 C.F.R. 1910.1030 (d)(2)(viii); work practice controls (such as the requirement that employees wash their hands and other skin immediately after contact with blood or other potentially infectious materials), *id.* § 1910.1030 (d)(2)(vi); requirements for personal protective equipment such as gloves and gowns, *id.* § 1910.1030(d)(3)(i); and housekeeping requirements covering the cleaning of contaminated surfaces and laundry and the disposal of contaminated waste, *id.* § 1910.1030(d)(4). See Pet. App. 3a-4a. In addition, the standard requires employers to offer employees, at the employer's expense, the opportunity to receive a Hepatitis B vaccine. 29 C.F.R. 1910.1030(f)(1); Pet. App. 4a. Also, employees involved in an "exposure incident," such as a needlestick, must be offered (at no employee expense) confidential bloodtesting, medical evaluation and counseling, and, if warranted, post-exposure prophylaxis. 29 C.F.R. 1910.1030(f)(3)(iii)-(vi).

c. In promulgating the standard, OSHA determined that bloodborne pathogens posed a significant risk of material health impairment to employees and

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[3] The CDC guidelines, while generally exempting saliva from the list of body fluids to which universal precautions apply, recommended "special precautions" for dental workers exposed to saliva from patients. See Pet. App. 8a.

that the standard was reasonably necessary or appropriate to eliminate or substantially reduce that risk. See generally *American Textile Mfrs. Inst., Inc.* v. *Donovan*, 452 U.S. 490, 506 (1981) (*Cotton Dust*); *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Inst.*, 448 U.S. 607, 614-615, 639, 642-643 (1980) (plurality opinion) (*Benzene*). The agency specifically found that a number of epidemiological studies demonstrated an increased prevalence of Hepatitis B markers in the blood of health care workers with exposure to blood, 56 Fed. Reg. 64,024; that it is the exposure to blood that places health care employees at risk and not some other factor, *ibid.*; and that because it takes only one exposure to infected blood to transmit the virus, any worker with exposure to blood is at risk of infection, *id.* at 64,056.

In finding that the risk of HBV is significant, the agency undertook a quantitative assessment of the risk to health care workers. Based on data gathered by the CDC, OSHA calculated that over a 45-year working lifetime, 83 to 113 of every 1000 non-immune health care workers would suffer HBV infection, 21 to 30 of these would develop clinical illness, 4 to 6 would be hospitalized, and 2 to 3 would die. Pet. App. 90a; 56 Fed. Reg. 64,028-64,029, 64,035. Occupationally acquired HBV kills about 200 health care workers in the United States annually. Pet. App. 3a.

OSHA also determined that, although vaccination greatly reduces the risk of HBV infection, a significant risk from HBV infection would exist even if all workers received an HBV vaccination. Assuming universal inoculation and a 96% vaccine efficacy rate, OSHA found that 3 to 5 of every 1000 health care workers still would be infected by HBV in a working

lifetime, and that one of those would contract a clinical illness. 56 Fed. Reg. 64,030, 64,037. OSHA further noted, however, that voluntary vaccination programs had not achieved a 100% acceptance rate, and based on data concerning the numbers of employees vaccinated under voluntary programs, the agency determined that the acceptance rate would average only 50% among all of the workers within the scope of the standard. *Id.* at 64,030.

Although the agency issued more detailed findings on HBV than on HIV, OSHA also concluded that available data showed that a risk of occupational HIV transmission exists for health care workers.[4] The agency determined that the data did not permit a quantitative assessment of that risk, 56 Fed. Reg. 64,034, but the "strong qualitative evidence that HIV can be transmitted in the workplace * * * serve[s] to * * * illustrate [the] risk remaining after the major protection measure of HBV vaccination is implemented." *Id.* at 64,036.

OSHA further determined that its assessment of significant risk of material impairment of worker health justified imposition of a standard based on a worker's occupational exposure to blood, without regard to the worker's particular occupation or workplace setting. OSHA noted that "[h]aving specific quantitative data for non-health care workers and for particular occupations and locations would add more precision to the quantitative risk assessment, but that level of detail is not possible, given the data

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[4] As of the close of the rulemaking record in 1990, approximately 24 cases of occupational HIV infection of health care workers in the United States had been documented. 56 Fed. Reg. 64,014.

available in the [rulemaking] record, nor necessary to a finding of significant risk, especially when the risk of infection is based upon occupational exposure to blood or other potentially infectious materials." 56 Fed. Reg. 64,036.

Nevertheless, OSHA gave specific consideration to the dental sector of the health care industry. Pet. App. 7a-9a. The agency observed that "[d]entists, dental hygienists, dental assistants and dental laboratory technicians are continually exposed to blood and bloody saliva during almost all dental procedures"[5] and that the record contained many references to occupational Hepatitis B infections in dental health professionals. 56 Fed. Reg. 64,092.[6]

d. OSHA also discussed regulatory alternatives. In particular, it explained why a specific standard would be advantageous to enforcement of some protective measures against bloodborne pathogens under the Occupational Safety and Health (OSH) Act's "general duty" clause (29 U.S.C. 654(a)(1)). See 56 Fed. Reg. 64,007, 64,038. OSHA also concluded that

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[5] See also 56 Fed. Reg. 64,103 (quoting CDC guidelines stating that "[d]uring dental procedures, contamination of saliva with blood is predictable, trauma to health-care workers' hands is common, and blood spattering may occur").

[6] See generally 56 Fed. Reg. 64,092 (noting that many dentists remained unvaccinated against HBV and citing an article from the Journal of the American Dental Association stating that "[i]n the late 1970s, it became clear that dentists are at a risk three times greater than that of the general population for hepatitis B"). See also *Infection control recommendations for the dental office and the dental laboratory*, 116 J. A.D.A. 241, 241 (1988) ("Dental health care personnel have long been recognized to be at high risk for acquiring hepatitis B through contact with patients.").

voluntary adherence to "non-enforceable" CDC guidelines calling for universal precautions would "not result in an adequate level of protection to the nation's health care and public safety workforce." *Id.* at 64,087. OSHA also explained that it declined to impose a mandatory HBV vaccination program because not all workers are willing to be vaccinated because of medical, religious, or privacy reasons. *Id.* at 64,037, 64,088, 64,154-64,155. Furthermore, as noted, OSHA determined that a significant risk of HBV remained even with a universal vaccine and that the vaccine would not protect against other bloodborne pathogens, such as HIV. Therefore, the other requirements of the standard would be needed even if all workers were vaccinated. *Id.* at 64,037.[7]

2. On November 26, 1991, after the agency closed the rulemaking record but before the standard was promulgated, Congress enacted the Department of Labor Appropriations Act, 1992, Pub. L. No. 102-170, Tit. I, 105 Stat. 1107. That law directed OSHA to publish by December 1, 1991, a final rule on bloodborne pathogens, based on the agency's May 30, 1989, proposed standard. The statute further provided that, in the event the agency did not act by that date, the proposed standard would take effect until the agency issued a final rule. *Id.* § 100, 105 Stat. 1113-1114.

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[7] OSHA conducted an extensive analysis of the feasibility of the bloodborne pathogens standard. In particular, OSHA concluded that the expected compliance costs for a dentist's office will amount to less than one percent of total income and that this impact would not cause undue harm in this sector of the health care industry. 56 Fed. Reg. 64,080. Petitioner has not sought review of the court of appeals' ruling upholding this feasibility determination.

OSHA issued the bloodborne pathogens standard on December 6, 1991.

3. Pursuant to Section 6(f) of the OSH Act, 29 U.S.C. 655(f), petitioner sought review in the court of appeals of the standard as applied to dental health care settings.[8] The court of appeals rejected petitioner's challenge.

a. In affirming the agency's findings that the measures imposed by the standard would reduce a significant workplace risk to human health, the court of appeals concluded that "OSHA's evaluation of the effects of the rule, relying as it does on the undoubted expertise of the Centers for Disease Control, cannot seriously be faulted." Pet. App. 5a. The court noted OSHA's findings that the rule would eliminate between 113 and 129 annual deaths of health care workers from HBV, and between 187 and 197 deaths if individuals infected by health care workers were included. *Id.* at 4a-5a. And it noted that, although most of those deaths could be avoided by the HBV vaccine, "the vaccine is not a hundred percent effective and, more important, * * * many health care workers refuse to be vaccinated." *Id.* at 5a. The court thus concluded that the additional requirements of the rule, beyond the voluntary vaccination program, would have a "positive effect * * * on [HBV]" as well

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[8] As the court of appeals noted, most employers in the health care industry accepted OSHA's rule. Pet. App. 2a. In addition to petitioner, one other employer group—representing medical personnel employers (who supply health care workers on a temporary basis to hospitals and nursing homes) and home health employers (who supply such workers to patients at home)—challenged the rule. *Ibid.*

as on prevention of HIV, for which there is no vaccine. *Ibid.*

The court rejected petitioner's assertions that OSHA improperly "lumped [dental care employers] in with" medical professionals who are far more exposed to patients' blood. Pet. App. 7a. The court noted that OSHA "gave separate consideration to every point raised before it by the dental association." *Ibid.* Thus, OSHA pointed out that the saliva of dental patients frequently contains blood—even in such routine procedures as teeth-cleaning—and that it is possible that even a small quantity of blood can sometimes be infective. *Id.* at 7a-8a. That conclusion was supported as well, the court held, by CDC guidelines recommending "special precautions" for saliva in dental procedures, as opposed to saliva in other patient care contexts for which precautions against bloodborne pathogens are not advised. *Id.* at 8a.

In rejecting petitioner's assertion that OSHA impermissibly failed to disaggregate the risk "industry by industry," the court acknowledged that "OSHA cannot impose onerous requirements on an industry that does not pose substantial hazards to the safety or health of its workers merely because the industry is a part of some larger sector or grouping and the agency has decided to regulate at wholesale." Pet. App. 8a-9a. At the same time, however, the court observed that OSHA is not required to "proceed workplace by workplace, which in the case of bloodborne pathogens would require it to promulgate hundreds of thousands of separate rules." *Id.* at 9a. Here, the court concluded, the agency provided a rational explanation for its choice of a "happy

medium" between these two extremes. *Ibid.* Thus, OSHA explained that although the cost of compliance with the rule varies in readily determinable fashion from industry to industry,[9] the risk does not. Instead, that risk is associated with practices involving exposure to blood. And, the court noted, although the risk of blood spatters and needlesticks is greater in some medical procedures than others, a dental worker is as likely to be spattered by blood as many workers in doctors' offices or hospitals. The court thus concluded that "[t]he idea behind requiring universal precautions for health care workers is to protect those workers in any situation in which there is a nontrivial risk of physical contact with a patient's blood, and these situations arise in dentists' offices as well as in doctors' offices and hospitals." *Ibid.*[10]

b. Judge Coffey dissented in part. Although he acknowledged (Pet. App. 21a) that OSHA had power to regulate workplace safety, he suggested that Con-

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[9] The court specifically rejected petitioner's argument that the agency had improperly found the rule to be economically feasible for the dental sector of the health care industry. Pet. App. 12a. Noting that since, "[a]nnualized, [the costs of compliance] are estimated to be equal to less than one-third of one percent of the [dental] industry's annual revenues," such costs could "hardly be thought so great as to imperil dentistry." *Ibid.*

[10] Although it also upheld (Pet. App. 10a-12a) the specific components of the standard against petitioner's other challenges, the court of appeals vacated portions of the standard insofar as it applied to the medical personnel and home health care industries. The court held that OSHA had not adequately addressed feasibility concerns arising from the fact that employers in those industries do not control the worksites at which their employees work. *Id.* at 13a-16a.

gress should "address the question * * * whether OSHA [in addition to the CDC] is the proper agency to regulate health care." *Id.* at 19a; see also *id.* at 21a, 27a-28a, 30a-31a, 41a-44a, 48a n.27, 50a-52a.

Judge Coffey also concluded that OSHA improperly aggregated various sectors in the health care industry to arrive at an artificial risk level applicable to the industry as a whole. Pet. App. 21a-26a. Furthermore, Judge Coffey concluded that, in determining whether significant risks will be eliminated by the standard, the agency did not properly take into account the "current state of regulation," including "the CDC Guidelines adopted by the states," other individual state and professional regulations, and the increased use of HBV vaccinations in the dental profession. The failure to do so, he concluded, rendered the agency's rule arbitrary and capricious. *Id.* at 29a-30a. Judge Coffey also criticized the agency for failing to require mandatory vaccinations, which would in his view render the additional requirements of the standard unnecessary to protect against HBV. *Id.* at 32a-33a.[11]

ARGUMENT

The decision of the court of appeals upholding the application of OSHA's bloodborne pathogens standard to dental care employers is correct and does not conflict with any decision of this Court or any court of appeals. Accordingly, review by this Court is not warranted.

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[11] Judge Coffey also concluded, contrary to the majority, see note 9, *supra*, that the agency's feasibility analysis was fatally flawed because of its failure to take into account certain costs. Pet. App. 46a-50a.

1. Congress enacted the OSH Act "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources," 29 U.S.C. 651(b), and to that end gave the Secretary of Labor the authority to issue mandatory occupational safety and health standards. 29 U.S.C. 655(a) and (b). See also *Atlas Roofing Co.* v. *OSHRC*, 430 U.S. 442, 444-445 (1977). In promulgating a standard which deals with "toxic materials or harmful physical agents," Congress directed the Secretary to adopt the "standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." 29 U.S.C. 655(b)(5).

Under this Court's decisions in *American Textile Mfrs. Inst., Inc.* v. *Donovan*, 452 U.S. 490, 506 (1981) (*Cotton Dust*), and *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Inst.*, 448 U.S. 607, 614-615, 639, 642-643 (1980) (plurality opinion) (*Benzene*), before it may promulgate a standard, OSHA must determine that a substance poses a significant risk of material impairment to workers' health and that the standard is reasonably necessary or appropriate to eliminate or substantially reduce that risk. In requiring the Secretary to make a threshold finding of significant risk, however, this Court emphasized that the requirement is not a "mathematical straitjacket," that OSHA "is not required to support its finding * * * with anything approaching scientific certainty," and that a "reviewing court [is] to give OSHA some leeway where its findings must be made

on the frontiers of scientific knowledge." *Benzene*, 448 U.S. at 655-656 (plurality opinion). And, "so long as they are supported by a body of reputable scientific thought, the [a]gency is free to use conservative assumptions in interpreting the data * * *, risking error on the side of overprotection rather than underprotection." *Id.* at 656 (plurality opinion).

The court of appeals correctly ruled that OSHA made a significant risk finding that justified promulgation of the bloodborne pathogens standard generally and warranted application of the standard to workers in the dental care sector of the health care industry. OSHA found that unprotected exposure to blood creates a significant quantifiable risk of HBV infection, with the attendant potential for "material impairment of health or functional capacity," 29 U.S.C. 655(b)(5), including the risk of death. That finding was based on epidemiological studies demonstrating that health care workers become infected with HBV at a rate significantly greater than the general population. While not quantifiable, OSHA also determined that the available data demonstrate a risk of HIV transmission among health care workers. Finally, OSHA found that the risks from occupational contact with bloodborne pathogens could be substantially reduced by adoption of the standard. As the court of appeals concluded, those findings amply satisfy *Benzene*'s significant risk requirement.

Petitioner has not challenged the agency's findings for the health care industry generally. Rather, petitioner asserts (Pet. 12) that because OSHA failed to "disaggregate" the "24 [health care] industry sectors" and make a separate risk assessment for the dental care sector, the standard cannot reach

employees of dental employers. That contention, however, fundamentally misapprehends OSHA's significant risk assessment in this case. Based on the rulemaking record, including the epidemiological data on health care workers generally, OSHA found that any worker who has occupational exposure to blood faces a significant risk of HBV infection. The agency also determined, based on CDC findings, that saliva in dental procedures is a potentially infectious material because such saliva frequently contains blood.[12] The agency's detailed findings thus establish that dental care employees who in the course of their duties reasonably anticipate exposure to saliva face a significant risk of harm.

Petitioner's assertion (Pet. 12) that OSHA must in all circumstances disaggregate employer groupings by "industry" when making quantitative risk assessments is without support in the statute or case law. As the court of appeals recognized, OSHA must be provided leeway in determining the appropriate grouping of employers or employees that will yield a meaningful risk assessment in light of the standard at issue and the rulemaking record. Pet. App. 8a-9a. Thus, when OSHA finds a significant risk stemming from a work practice or work environment that is common to various industries,[13] it need not—

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[12] In its brief before the court of appeals, petitioner stated that 53.8% of annual patient visits to dentists involve exposure to blood, although that figure is reduced to 29.7% if periodontic, surgical, and restorative visits are excluded. Pet. C.A. Br. 10 & n.2.

[13] The statute makes clear that OSHA is authorized to adopt mandatory safety and health standards for particular

particularly in the absence of pertinent record evidence—quantify the risk for each affected industry.[14]

Benzene requires OSHA to find that exposure to a harmful substance is hazardous at a particular level, not that exposures at that level are hazardous in each industry in which exposure to that substance occurs. Similarly, in upholding OSHA's hazard communications standard, "a performance-oriented information disclosure standard covering thousands of chemical substances used in numerous industries," the Third Circuit rejected the argument that an industry-specific risk assessment was required, holding that "[f]or such a standard the significant risk requirement must of necessity be satisfied by a general finding concerning all potentially covered industries." *Associated Builders & Contractors, Inc.* v. *Brock*, 862 F.2d 63, 68 (3d Cir. 1988), certs. denied, 490 U.S. 1064, 1065 (1989), and 494 U.S. 1003 (1990). Indeed, a requirement that risk assessments must be industry-specific would "effectively cripple OSHA's

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"occupations" or "work environments" as well as for "particular industries." See 29 U.S.C. 655(g).

[14] Section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b)(5), requires OSHA to regulate workplace exposure to toxic substances and harmful physical agents based on the "best available evidence"—a task that allows it to "extrapolat[e] from limited data" and "fill gaps in knowledge with policy considerations." *AFL-CIO* v. *Marshall*, 617 F.2d 636, 651 (D.C. Cir. 1979), aff'd in part and vacated in part, *Cotton Dust*, 452 U.S. 490 (1981). See also *United Steelworkers* v. *Marshall*, 647 F.2d 1189, 1228 n.54 (D.C. Cir. 1980) (the standard of "best available evidence" permits OSHA "to act immediately to protect workers" even though contemporary science is unable to explain certain aspects of a problem), cert. denied, 453 U.S. 913 (1981).

performance of the duty imposed on it by 29 U.S.C. § 655(b)(5)," *ibid.*; it would also be unnecessary here, since all the covered employees engage in the same risk-creating work practice—exposure to blood.

In light of the agency's detailed significant risk findings for the bloodborne pathogens standard and its reasoned explanation for its coverage of the dental care sector of the health care industry, it is clear that the decision below does not conflict with the appellate decisions cited (Pet. 11) by petitioner. In *AFL-CIO* v. *OSHA*, 965 F.2d 962 (11th Cir. 1992), OSHA had promulgated a standard setting permissible exposure limits for 428 different air contaminants. In vacating that standard, the court of appeals concluded that "OSHA's discussions of individual substances generally contain no quantification or explanation of the risk from that individual substance." 965 F.2d at 975. The court of appeals thus believed that OSHA, in promulgating a multi-substance standard, had not adequately demonstrated significant risk for each substance. Here, by contrast, the agency provided extensive explanations, in both qualitative and quantitative terms, of the significant risks associated with occupational exposure to blood and other potentially infectious materials.

Nor does the decision below conflict with *International Union, UAW* v. *OSHA*, 938 F.2d 1310 (D.C. Cir. 1991). In that case, OSHA promulgated a "lockout/tagout" standard (requiring locking or tagging of energy sources for machinery during its service and maintenance in order to prevent the machinery's accidental activation) that applied to "virtually all equipment in almost all industries." 938 F.2d at 1312. The court of appeals ruled that OSHA

had inadequately explained its failure to disaggregate its significant risk findings by industry where there was record evidence of wide variations in injury rates among covered industries, including evidence that the injury rate in many of the covered industries was zero. Thus, the court directed OSHA on remand to explain how its aggregated approach conformed to the agency's interpretation of the OSH Act. *Id.* at 1322. In this case, the agency clearly explained its rationale for reliance on risk assessments derived from data on the health care industry generally, and gave specific reasons why such determinations should be applied to the dental sector. Indeed, there was evidence in the rulemaking record that dental care personnel are at a considerably higher risk of acquiring HBV infection than the general population. See note 6, *supra*.[15]

2. Petitioner contends (Pet. 13-14) that OSHA failed to determine whether the rule's requirements are cost-effective when compared to regulatory alternatives and that, had the agency done so, it would have mandated only a program of mandatory vaccination for HBV. That is because, in petitioner's view, mandatory vaccination would "virtually elim-

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[15] Petitioner's citation (Pet. 12) of decisions addressing OSHA's feasibility determinations does not support its argument. As the court below recognized (Pet. App. 8a), even where an OSHA standard focuses on a work practice or work environment condition that cuts across industries, OSHA's feasibility determination will often need to focus on an industry group. In fact, OSHA made a specific determination that the bloodborne pathogens standard would not be infeasible for dental employers in this case, and petitioner does not now challenge that determination.

inate" the risk of HBV, which petitioner characterizes as "the sole justification for the final rule." Pet. 14.

In *Cotton Dust*, this Court held that OSHA need not (and indeed may not) engage in cost-benefit analysis in deciding whether to promulgate a health standard under Section 6(b)(5) of the Act. Rather, in protecting workers from significant risks in the workplace, the agency must issue the rule that is most worker-protective within the limits of technological and economic feasibility, and need not "demonstrate that the reduction in risk of material health impairment is significant in light of the costs of attaining that reduction." 452 U.S. at 506. The Court in *Cotton Dust* reserved the further question whether Section 3(8) of the Act, 29 U.S.C. 652(8), which requires a standard to be "reasonably necessary or appropriate to provide safe or healthful employment," obliges OSHA in promulgating a Section 6(b)(5) standard to choose the least costly of two regulatory methods that "achieve the same reduction in health risk." 452 U.S. at 513 n.32.

In this case, OSHA considered various regulatory alternatives and determined that they were not equally effective in reducing the risk from bloodborne pathogens. Thus, it need not have considered the question of the cost-effectiveness of competing alternatives. Cf. *Building & Constr. Trades Dep't, AFL-CIO* v. *Brock*, 838 F.2d 1258, 1269 (D.C. Cir. 1988). OSHA rejected reliance on HBV vaccination alone because the HBV vaccination is not entirely effective, and because the additional requirements of the standard, such as workplace controls and personal protective equipment, would still be necessary to

reduce the significant risk of HBV infection that would remain after universal vaccination of workers. See pp. 5-6, 8, *supra*. Also, OSHA had two additional reasons for rejecting a mandatory vaccination scheme in favor of a voluntary vaccination scheme complemented by workplace controls: the workplace controls will provide substantial protection against infection by HIV and other bloodborne pathogens, and OSHA, as a matter of regulatory policy, did not wish to force workers unwilling to take the vaccine for medical, religious, or other reasons to submit to vaccinations. The agency thus acted well within the "zone of reasonableness" in adopting the bloodborne pathogen standard. *Forging Indus. Ass'n* v. *Secretary of Labor*, 773 F.2d 1436, 1443 (4th Cir. 1985) (en banc).

3. Petitioner errs in contending (Pet. 14-16) that further review is warranted because the court of appeals failed properly to review the record and determine whether OSHA's findings and determinations underlying the standard are supported by substantial evidence. This Court has stated that, because "the [OSH] Act places responsibility for determining substantial evidence questions in the courts of appeals," the Court "'will intervene only in what ought to be the rare instance when the [substantial evidence] standard appears to have been misapprehended or grossly misapplied' by the court below." *Cotton Dust*, 452 U.S. at 523, quoting *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 491 (1951). Petitioner falls far short of any showing that the court of appeals misapprehended or grossly misapplied the standard of review.

In support of its position (Pet. 14) that the court of appeals "took a hands off approach to the bloodborne pathogens rule" and neglected to conduct substantial evidence review, petitioner relies on statements by the court deferring to OSHA's expertise and its policy-making role and noting the limited role of the judiciary in reviewing such decisions. Such deference, however, is entirely consistent with the substantial evidence standard of review, and with the burden of proof outlined in this Court's decision in *Benzene*. See 448 U.S. at 656 (plurality opinion) ("OSHA is not required to support its finding * * * with anything approaching scientific certainty"; "a reviewing court [must] give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge"); see also *International Union, UAW* v. *Pendergrass*, 878 F.2d 389, 392 (D.C. Cir. 1989) ("our deference to the agency is at a peak for its choices among scientific predictions"); *National Grain & Feed Ass'n* v. *OSHA*, 866 F.2d 717, 729 (5th Cir. 1989); *Public Citizen Health Research Group* v. *Tyson*, 796 F.2d 1479, 1485 (D.C. Cir. 1986); *Forging Indus. Ass'n*, 773 F.2d at 1443.

Furthermore, petitioner's selective quotation (Pet. 15) from the court of appeals' opinion erroneously suggests that the panel majority found OSHA's fact-finding deficient, but nonetheless upheld the rule. In fact, the court of appeals explained why none of the perceived shortcomings altered the validity of the agency's conclusions. Rather than demonstrating that the court of appeals failed to review the record, those passages show that the court carefully reviewed the agency's findings. Although it detected some minor flaws, they did not draw into question the

action taken by the agency. Moreover, on the issues that are the focus of this petition—OSHA's application of its significant risk finding to dental care workers and its conclusion that a vaccination program by itself would have been insufficient—the court of appeals expressed no reservations whatsoever as to OSHA's fact-finding. Pet. App. 5a, 8a-10a.

4. Petitioner briefly argues (Pet. 10-11) that OSHA failed adequately to take the effects of preexisting regulation—including CDC guidelines and the OSH Act's general duty clause[16]—into account when it determined bloodborne pathogens posed a "significant risk" to workers in the health care industry.

The question whether OSHA must "consider existing controls before imposing costly and burdensome new requirements on industry" (Pet. 11) is not fairly included in the three questions presented in the petition, and further review to consider that question would therefore be unwarranted. See Sup. Ct. R. 14.1(a). Petitioner chose to present the questions whether OSHA committed error in failing to make a separate "significant risk" finding for the dental care sector, whether OSHA neglected an alternative regulation that allegedly would have been more cost-effective, and whether the court of appeals departed from accepted standards used in conducting "substantial evidence" review. See Pet i. The question whether OSHA erred in failing to assess the effects

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[16] The general duty clause requires each employer to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm." 29 U.S.C. 654(a)(1).

of pre-existing regulatory measures—none of which appear to apply distinctively to employment in dental care—does not appear to be fairly included within any of those questions.

In any event, petitioner's argument that OSHA erred is mistaken. Contrary to petitioner's contention, OSHA did specifically consider existing regulatory efforts to reduce risks from bloodborne pathogens. The agency explained that a specific bloodborne pathogen standard would promote reduction of risks beyond the reduction achieved by OSHA's enforcement under the general duty clause and beyond any level of voluntary compliance by employers with CDC guidelines. 56 Fed. Reg. 64,007, 64,038.[17]

Moreover, there is no support in the statute or case law for petitioner's contention that before OSHA may issue a specific standard it must demonstrate (let alone quantify) that case-by-case adjudication under the general duty clause has been insufficient to eliminate the risk. The statute provides OSHA with

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[17] Specifically, OSHA found that a standard would give more guidance to employers on the precautions needed to avoid bloodborne pathogens infection, would require more abatement methods than the general duty clause and the general industry standards, and would reduce the litigation burden on OSHA and employers. Moreover, the 23 States and two territories with OSHA-approved state plans are required to adopt standards at least as effective as federal OSHA standards but are not required to adopt or enforce general duty provisions. See generally *Gade* v. *National Solid Wastes Management Ass'n*, 112 S. Ct. 2374, 2382 (1992) (plurality opinion). The adoption of a federal OSHA standard therefore would provide more protection for employees in those jurisdictions. 56 Fed. Reg. 64,007.

the authority to issue mandatory health and safety standards, and Congress envisioned that specific standards that the agency develops through the rulemaking process would be the mainstay of OSHA regulation. S. Rep. No. 1282, 91st Cong., 2d Sess. 10 (1970) ("[t]he general duty clause in this bill would not be a general substitute for reliance on standards, but would simply enable the Secretary to [e]nsure the protection of employees who are working under special circumstances for which no standard has yet been adopted"); H.R. Rep. No. 1291, 91st Cong., 2d Sess. 21-22 (1970) ("th[e] [general duty] clause enables the Federal Government to provide for the protection of employees who are working under such unique circumstances that no standard has yet been enacted to cover this situation" (emphasis omitted)). See also *Usery* v. *Marquette Cement Mfg. Co.*, 568 F.2d 902, 905 n.5 (2d Cir. 1977). Congress envisioned the general duty clause as a supplement to, not a substitute for, mandatory standards.

Petitioner similarly errs in suggesting (Pet. 10-11) that OSHA should have analyzed the possible future reduction in risk of HBV that would result from Congress's passage of Pub. L. No. 102-141 requiring States, upon pain of losing certain federal funding, to issue guidelines consistent with CDC guidelines.[18]

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[18] Pub. L. No. 102-141, enacted on October 28, 1991, requires state public health officials, on pain of losing funds provided to their State under the Public Health Service Act, to issue, within one year of the law's enactment, guidelines covering health professionals practicing within their State which are equivalent to those promulgated by the CDC "concerning recommendations for preventing the transmission of [HIV] and [HBV] during exposure prone invasive procedures." Treasury,

Had OSHA awaited the development of epidemiological data reflecting the effects of possible changes on practices resulting from that law—which did not even require state compliance until a year after the law's passage, and which permitted States to obtain extensions from that deadline, see Pet. 5—promulgation of the bloodborne pathogens standard would have been delayed for years. Adoption of that approach would have put the agency on a collision course with Congress's subsequent mandate in Pub. L. No. 102-170 to issue by December 1, 1991, a bloodborne pathogens standard based on OSHA's proposed standard. OSHA, instead, acted properly and in conformance with Congress's mandates in Pub. L. No. 102-170 and the OSH Act itself by issuing a bloodborne pathogens standard based on "the best available evidence," 29 U.S.C. 655(b)(5)—the 1988 CDC epidemiological data and other record evidence from the rulemaking proceeding.[19]

Postal Service and General Government Appropriations Act, 1992, Pub. L. No. 102-141, § 633, 105 Stat. 876.

[19] Petitioner's reliance (Pet. 11) on this Court's decision in *Benzene* as support for its position is entirely misguided. In *Benzene*, the Court held that OSHA could not reduce the permissible exposure limit for a toxic substance, benzene vapor, without first showing that the existing exposure limit is unsafe. 448 U.S. at 644-645 (plurality opinion). OSHA complied with *Benzene* in this rulemaking by determining that there existed a significant risk of harm from occupational exposure to bloodborne pathogens. *Benzene* in no way suggests that there are any limitations on OSHA's authority to adopt a standard in lieu of a general duty clause enforcement policy, or that OSHA is required to account for the future effects of future state regulation of a hazardous substance.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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